

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 22nd 2005

IFW

Jacquelyn P. Bolin

Jacquelyn P. Bolin



Attorney Docket No. CHM-015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
Prasad DEVARAJAN et al. : Confirmation No. 2792
Serial No.: 10/811,130 : Group Art Unit 1653
Filed: March 26, 2004 :
A METHOD AND KIT FOR DETECTING THE EARLY
ONSET OF RENAL TUBULAR CELL INJURY

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR 1.56, 1.97 and 1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the above-identified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

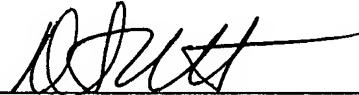
This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

This submission does not represent that a search has been made or that no closer art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully submitted,

For: Prasad DEVARAJAN et al.

By 
Daniel F. Nesbitt
Attorney for Applicant
Registration No. 33,746
(513) 229-0383
Customer Number 38155

November 22, 2005

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

Application Number	10/811,130
Filing Date	03/26/2004
First Named Inventor	DEVARAJAN et al.
Art Unit	1653
Examiner Name	
Attorney Docket Number	CHM-015

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 5,627,034	05/06/1997	Gould et al.	
		US- 5,814,462	09/29/1998	Weinberger	
		US- 6,136,526	10/24/2000	Venge	
		US- 6,447,989	09/10/2002	Comper	
		US- 6,461,827	10/08/2002	Oda et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 01/55210	08/02/2001	Munin Corporation		
		WO 03/068054	08/21/2003	The Government of the United States of America as represented by The Secretary, Department of Health Services		
		WO 2004/005540	01/15/2004	Metagen Pharmaceuticals GMBH		
		WO 2004/005544	01/15/2004	Novartis AG		
		WO 2005/024054	03/17/2005	Royal Women's Hospital		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
		BAILLY, V., et al., Shedding of Kidney Injury Molecule-1, a Putative Adhesion Protein Involved in Renal Regeneration; The Journal of Biological Chemistry, Vol. 277, No. 42, Issue of October 18, pp. 39739-39748, 2002	
		CARLSON, M., et al., Human neutrophil lipocalin is a unique marker of neutrophil inflammation in ulcerative colitis and proctitis, Gut 2002; 50:501-506	
		EICHLER, I., Human neutrophil lipocalin, a highly specific marker for acute exacerbation in cystic fibrosis, Eur Respir J 1999; 14: 1145-1149	
		HAN, W. K., et al., Kidney Injury Molecule-1(KIM-1): A novel biomarker for human renal proximal tubule injury; Kidney International, Vol. 62 (2002), pp. 237-244	
		ICHIMURA, T., et al., Kidney Injury Molecule-1 (KIM-1), a Putative Epithelial Cell Adhesion Molecule Containing a Novel Immunoglobulin Domain, is Up-regulated in Renal Cells after Injury, The Journal for Biological Chemistry, Vol. 273, No. 7, Issue of February 13, pp. 4135-4142, 1998	
		MALLBRIS, L., et al, Neutrophil gelatinase-associated lipocalin is a marker for dysregulated keratinocyte differentiation in human skin, Experimental Dermatology, Vol. 11, Issue 6 Page 584 – December 2002	Abstract
		MISHRA, J., et al, Amelioration of Ischemic Acute Renal Injury by Neutrophil Gelatinase-Associated Lipocalin; J. Am. Soc Nephrol 15:3073-3082, 2004	
		MISHRA, J., et al, Neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for acute renal injury after cardiac surgery, The Lancet, Vol. 365, April 2, 2005, pp. 1231-1238	
		MISHRA, J., et al., Neutrophil Gelatinase-Associated Lipocalin: A Novel Early Urinary Biomarker for	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				<i>Complete if Known</i>	
Sheet	2	of	2	Application Number	10/811,130
				Filing Date	03/26/2004
				First Named Inventor	DEVARAJAN et al.
				Art Unit	1653
				Examiner Name	
				Attorney Docket Number	CHM-015

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.			T ²
		ODA, H., et al. Development and Evaluation of a Practical ELISA for huan Urinary Lipocalin-Type Prostaglindin D. Synthase, Clincal Chemistry 48:9 1445-1453 (2002)			
		VINAYAK, S., et al., Prevalence of the K76T mutation in the <i>pf crt</i> gene of <i>Plasmodium falciparum</i> among chloroquine responders in India, Acta Tropica, Volume 87, Issue 2, July 2003, pp. 287-293			Abstract
		XU, S., Lipocalins as biochemical markers of disease, Biochimica et Biophysica Acta 1482 (2000) 298-307			

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

COPENDING U.S. PATENT APPLICATION				
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
	DEVARAJAN, et al.	11/096,113	03/31/2005	CHM-025M

Examiner Signature		Date Considered	
--------------------	--	-----------------	--